

CLAIMS

1. Ready-for-use injectable solution, characterized by:
 - a) Comprising 9-((1,3-DIHYDROXYPROPAN-2-IL OXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE as its free acid form;
 - 5 b) Being prepared as a ready-for-use pre-diluted solution in glucose 5% or sodium chloride 0.9% aqueous solution;
 - c) Presenting a pH ranging from about 3.0 to about 7.5;
 - 10 d) Being sterile;
 - e) Being stable for at least 24 months.
2. Injectable solution according to claim 1, characterized by being prepared as a ready-for-use pre-diluted solution in glucose 5% aqueous solution.
- 15 3. Injectable solution according to claim 2, characterized by presenting a pH ranging from about 3.0 to about 7.0.
4. Injectable solution according to claim 3, characterized by presenting a pH ranging from about 3.2 to about 6.5.
5. Injectable solution according to claim 1, characterized by being prepared as a ready-for-use pre-diluted
20 solution in sodium chloride 0.9% aqueous solution.
6. Injectable solution according to claim 5, characterized by presenting a pH ranging from about 4.0 to about 7.5.
7. Injectable solution according to claim 6, characterized by presenting a pH ranging from about 4.5 to about 7.0.
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8. An inert closed system for packing a ready-fro-use injectable solution as described in claim 1, characterized by comprising a flexible bag manufactured by a tri-laminated material presenting clearness,

thermal and mechanical resistance, and impermeableness properties.

9. Closed system according to claim 8, characterized by that tri-laminated material is a composition of three distinct layers, being an external layer of polyester,
5 an intermediate layer of polyethylene and the inner layer of propylene copolymer.
10. Closed system according to claim 9, characterized by being the polyester layer heat resistant with mechanical or abrasive resistant properties, the
10 polyethylene layer affording flexibility and works as a barrier against moisture and vapor exchanging with the environment, and the polyester copolymer layer being chemically inert in contact with the packed material,
15 being impermeable and highly flexible.
11. Process for eliminating alkaline residues from 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE, characterized by comprising the following steps:
 - a) Suspending the 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)
20 METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE in demineralized water;
 - b) Elevating the pH to a range between 10.5 and 12.5 by adding inorganic bases;
 - c) Elevating the temperature of the resulting
25 solution 11(b) to a range between 75° and 90°C
 - d) Adding inorganic or organic acids adjusting the pH in a range from 4.5 to 5.5;
 - e) Cooling the solution to a temperature ranging from
30 5° to 7°C and keeping the resulting crystals of 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE under stirring for 25 to 40 minutes;

- f) Filtering the resulting crystals from 11(e) and washing with an organic solvent selected from the group comprising acetone, ethanol, methanol and isopropanol;
- 5 g) Intense refluxing the resulting crystals from 11(f) in an organic solvent selected from the group comprising methanol, ethanol, propanol, isopropanol and butanol, for a period of time ranging from 3 to 4 hours;
- 10 h) Cooling the resulting suspension from 11(g) to a temperature ranging from 20° and 30°C, filtering the crystals and drying them under vacuum and under a temperature ranging from 60° and 80°C.
12. Process according to claim 11, characterized by the
15 inorganic base used in 11(b) being selected from the group comprising potassium hydroxide, lithium hydroxide and sodium hydroxide.
13. Process according to claim 12, characterized by the inorganic base is sodium hydroxide.
- 20 14. Process according to claim 11, characterized by the organic solvent used in steps 11(f) and 11(g) is isopropanol.
15. Pharmaceutical presentation sterile, stable, ready for the therapeutic administration, characterized by
25 comprising as active pharmaceutical ingredient the 9-((1,3-DIHYDROXYPROPAN-2-IL OXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE as its free acid form, being constituted by an injectable sodium chloride 0.9% or glucose 5% aqueous solution, presenting a pH ranging from about
30 3.0 to 7.5, and being packed in a special packing, which is a flexible bag manufactured with a tri-laminated material.

16. Pharmaceutical presentation according to claim 15, characterized by the solution is a sodium chloride 0.9% solution, the pH is within the range of about 4.0 to about 7.5, and by being stable for at least 24 months when stored under room temperature.
17. Pharmaceutical presentation according to claim 16, characterized by the pH is within the range of about 4.5 to about 7.0.
18. Pharmaceutical presentation according to claim 15, characterized by the solution is a glucose 5% solution, the pH is within the range of about 3.0 to 7.0, and by being stable for at least 24 months when stored under room temperature.
19. Pharmaceutical presentation according to claim 18, characterized by the pH is within the range of about 3.2 to about 6.5.
20. Pharmaceutical presentation according to claim 15, characterized by the active pharmaceutical crystals of 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE as its free acid form are free from alkaline residues.
21. Pharmaceutical presentation according to claim 20, characterized by the active pharmaceutical crystals of 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE are resulting from the process described in claim 11.
22. Pharmaceutical presentation according to claim 15, characterized by the packing tri-laminated material used in the manufacturing of the flexible bags is a composition of three distinct layers, being an external layer of polyester, an intermediate layer of

polyethylene and the inner layer of propylene copolymer.

23. Pharmaceutical presentation according to claim 15,
characterized by the flexible bag manufactured by a
5 tri-laminated material being inert in contact with the
solution, clearness, possessing thermal, mechanical and
abrasive resistance, and being impermeable configuring
a closed system.
24. Use of the closed system as described in claim 8,
10 characterized by being for packing glucose 5% or sodium
chloride 0.9% aqueous solutions comprising 9-((1,3-
DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-
ONE.
25. Use of the closed system as described in claim 24,
15 characterized by 9-((1,3-DIHYDROXYPROPAN-2-
ILOXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE crystals are
treated according to the process for eliminating
alkaline residues as described in claim 11.
26. Use of the injectable solution from claim 1,
20 characterized by being in the treatment of
immunodepressed patients carrying viral infections.
27. Use according to claim 26, characterized by being in
the treatment of AIDS carrying individuals and
immunotransplanted.
- 25 28. Use according to claim 26, characterized by being in
the fight against a wide spectrum viral infections
including Epstein-Barr virus, cytomegalovirus,
adenovirus, herpes zoster virus and herpes virus type 1
and 2.
- 30 29. Use of the closed system from claim 8, characterized by
being in the treatment of immunodepressed patients
carrying viral infections.

30. Use according to claim 29, characterized by being in the treatment of AIDS carrying individuals and immunotransplanted.
31. Use according to claim 29, characterized by being in the fight against a wide spectrum viral infections including Epstein-Barr virus, cytomegalovirus, adenovirus, herpes zoster virus and herpes virus type 1 and 2.
32. Use of the 9-((1,3-DIHYDROXYPROPAN-2-IL OXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE crystals, free from alkaline residues prepared according to claim 11, characterized by being used to prepare pre-diluted glucose 5% and sodium chloride 0.9% solutions to be used in the treatment of immunodepressed patients carrying viral infections.
33. Use according to claim 32, characterized by being in the treatment of AIDS carrying individuals and immunotransplanted.
34. Use according to claim 32, characterized by being in the fight against a wide spectrum viral infections including Epstein-Barr virus, cytomegalovirus, adenovirus, herpes zoster virus and herpes virus type 1 and 2.
35. Use of the pharmaceutical presentation from claim 15, characterized by being in the treatment of immunodepressed patients carrying viral infections.
36. Use according to claim 35, characterized by being in the treatment of AIDS carrying individuals and immunotransplanted.
37. Use according to claim 35, characterized by being in the fight against a wide spectrum viral infections including Epstein-Barr virus, cytomegalovirus,

adenovirus, herpes zoster virus and herpes virus type 1 and 2.

38. Method for treating patients with viral infections, characterized by consisting of administering a medicament prepared as an injectable solution according to claim 1.

39. Method for treating patients with viral infections, characterized by consisting of using a pharmaceutical presentation prepared according to claim 15.